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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,336	02/23/2004	Glen E. Jorgensen	47168-00158USD1	8712

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EXAMINER	
CHAPMAN, GINGER T	
ART UNIT	**PAPER NUMBER**
3761	

MAIL DATE	DELIVERY MODE
08/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,336	JORGENSEN ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5 and 8-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *4,5,8-10,12,13 and 15-18* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 July 2007 has been entered.

Status of the claims

By way of Applicants' amendment filed 30 July 2007: claims 17 and 18 are added; claims 4, 5 and 8-18 are pending in the application.

Claim Objections

Claim 4 is objected to because of the following informalities: the examiner notes that claim 4 status identifier states that claim 4 is (Previously Presented) however the claim is amended therefore the correct status identifier would properly be (Currently Amended).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 5, 8-10, 12-13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (4,828,716) in view of in view of Coleman (US 3,508,653) in view of Kelly et al. (6,074,883) and further in view of Furse (US 5,354,483).

With regard to **claims 4-5 and 16**, McEwen discloses a method wherein blood is collected from a patient using a needle set and collected or transferred into a container and tubing is connected to the container for delivery and withdrawal of components. The container has a piston (closure 16) that moves as a result of the centrifugation to separate the blood into its components. The container is placed within a centrifuge for a spin to separate the blood into its components. McEwen teaches that the separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container). See figures la-lg; col. 7, line 28 to col. 9, line 49. McEwen also teaches that the components may be further separated by centrifugation until desired separation of components is achieved. Col. 14, lines 43-51.

McEwen et al disclose the method substantially as claimed except for disclosing specifically the following: the step of attaching a hollow plunger rod with a port to displace separated platelet-poor plasma by moving the plunger toward the first port; a "soft" and "heavy" spin; that the separated red blood cells are expelled is into a waste bag; or that the collection container contains a small amount of anti-coagulant.

Coleman discloses a method of collecting and separating a patient's blood. At c. 6, ll. 63-69, Coleman teaches the plunger and rod comprising second and third ports, thus disclosing a desire for such. Coleman teaches that the plunger can comprise a hollow rod having a second and third port, i.e. the ports on either end of the axial passageway comprising the plunger, and teaches displacing the separated platelet poor plasma by moving expelling the plasma through

the second and third ports of the plunger rod thereby separating and decanting the blood products (c. 6, ll. 63-69). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plunger rod of McEwan having a third port therein as taught by Coleman since Coleman states at c. 6, ll. 63-69 that the benefit of practicing the method with this step is that it permits the passage of the light phase, i.e. the plasma, upwards through the plunger rod such that it can be removed from the chamber.

With respect to the limitation of **claims 4 and 16: step (b)**, transferring the blood from the needle through the tubing, fitting and first port into the container by moving the plunger away from the first port, Coleman teaches at c. 5, ll. 60-66 that if the tube or chamber has been previously evacuated then blood will flow from the individual through a needle into the collection tube as the vacuum draws blood through the ports and into the tubing. Additionally, it is known in the blood withdrawal art that moving the plunger within a syringe chamber causes the blood to flow toward the plunger by means of the reduction in pressure created by moving the plunger, again as the vacuum created draws blood through the ports and into the tubing. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the step of transferring the withdrawn blood from the patient into the blood separation chamber necessarily and inevitably results in the blood being transferred though tubing and a port since all of the components are fluidly connected in serial.

With respect to the limitation of **claim 5, steps b, c and d**, McEwan in view of Coleman disclose the claimed invention but do not expressly disclose opening valves positioned within ports. Furse, at c. 1, ll. 17-20, expresses the desire to provide means for separating a patient's blood wherein the chamber has ends separated by a displacing plunger such that a first end of

chambers can receive the blood and a pre-selected phase of the blood may be received from the other end. As seen in Figures 1 and 3a, Furse teaches opening a valve (14) positioned within first port (54) whereby blood is transferred into first port (14) by moving plunger (18) away from the first port and closing the valve (c. 9, ll. 14-17; c. 8, ll. 47-55). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the methods of McEwan/Coleman to include the step of transferring the blood into the container as taught by Furse since Furse states at c. 9, ll. 10-15 that the benefit of performing the method in this manner is that blood can be introduced into the container and thereafter separated into phases.

With respect to **claims 8 and 9**, McEwen teaches that the centrifuge has a motor and control device that can control the speed as desired. Therefore, a "soft" and "heavy" spin may be achieved by the method of McEwen. Since McEwen teaches that separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container) it would be an obvious step in such a method to choose to decant separated red blood cells into a bag to one having ordinary skill in the art. If red blood cells are not the desired end product of the method, there would be no reason to keep them and decanting or expelling them into a waste container is standard operating procedure in medical laboratories. With respect to using a waste bag, a container is an equivalent to a bag.

With respect to **claims 10 and 13**, it would have been obvious to perform the displacing step manually or automatically since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art, *In re Venner*, 120 USPQ 192.

Applicant has provided no criticality for the step to be performed manually or automatically, the specification contains no disclosure of either the critical nature of the claim limitations nor any unexpected results arising therefrom, and that as such the limitations were arbitrary and therefore obvious. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with performing the step either manually or automatically because both perform the same function of displacing the cells and plasma, and in the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ.

With respect to **claims 12 and 15**, it would have been obvious step to one having ordinary skill in the art to include an anti-coagulant in the container since it is standard operating procedure in blood collection.

With regard to claims **17 and 18**, reciting the limitations of the ports including valves, the method comprising the steps of opening the valves, opening and closing valves are known from everyday use and therefore the step of opening valves would be obvious to one of ordinary skill in the art at the time the invention was made, for detailed discussion of opening the valves, see also claim 5, steps b, c and d, detailed *supra*.

Allowable claims

Claim 11 is allowed.

The following is an examiner's statement of reasons for allowance: The subject matter not found was the step of displacing red blood cells, platelet-rich plasma, and platelet-poor

plasma automatically in a centrifuge that facilitates opening the ports in combination with the other steps (or elements) in the claim reciting displacing the cells from the container by moving the plunger and expelling the cells through the tubing attached to the port.

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The subject matter not found was the step of displacing red blood cells, platelet-rich plasma, and platelet-poor plasma automatically in a centrifuge that facilitates opening the ports in combination with the other steps (or elements) in the claim reciting displacing the cells from the container by moving the plunger and expelling the cells through the tubing attached to the port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Levine (US 5,707,876) Figures 1-3.

Ayres (US 3,887,466) Figures 1-2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
08/18/07

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8/19/07